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| APPLICATION NO.                        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/847,102                             | 05/01/2001  | Dennis A. Carson     | 066778-0397         | 5759             |
| 41552                                  | 7590        | 11/13/2008           | EXAMINER            |                  |
| MCDERMOTT, WILL & EMERY                |             |                      | YU, MISOOK          |                  |
| 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 |             |                      |                     |                  |
| SAN DIEGO, CA 92122                    |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1642                |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 11/13/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/847,102             | CARSON ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MISOOK YU              | 1642                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 August 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-8, 16, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 16, 28 and 29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Claims 1-8, 16, 28, and 29 are pending and under consideration

### ***Claim Rejections - 35 USC § 112, Withdrawn***

The new matter rejection of claims 1-8, 16, 28, and 29 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** because applicant's argument is persuasive.

### ***Claim Rejections - 35 USC § 103***

Claims 1-8, 16, 28, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (IDS, #1711998, Proc. Natl. Acad. Sci. USA. vol. 95, pages 10164-9) in view of US Pat. 5,677,171 (IDS, Hudziak et al., Oct. 14, 1997).

Claims 1-8, 16, 28, and 29 are drawn to a purified antibody binds to an epitope at the N-terminal extracellular domain (SEQ ID NO: 68) or pharmaceutical comprising said antibody, wherein the antibody inhibits growth of a malignant cell expressing a frizzled 5 receptor.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant also argues that Tanaka reference teaches away from the claimed invention, because the reference only teaches Frizzled 3 being expressed in the cancer.

These arguments have been fully considered but found unpersuasive, because the instant specification is mostly about frizzled 2 being expressed on a malignant cell and only antibody being disclosed in the instant specification is anti-frizzled 2. The instant specification does not disclose any antibody that binds to SEQ ID NO: 68, nor discloses frizzled 5 protein being expressed in malignant cells. The extracellular domain of the protein called frizzled 5 protein disclosed in Tanaka et al., and the instantly claimed antibody binds have the same structure. Tanaka et al., at the paragraph bridging pages 10164-5 teach that N-terminal extracellular domain of a frizzled receptor lies just before the first transmembrane helix, also teach “the ectodomain of Fz functions as natural antagonist of Fz-mediated signal transduction”. Tanaka et al., at page 10164 teach Wnt binds to Frizzled family of seven-transmembrane proteins, and the seven-transmembrane proteins frizzled family proteins act as receptors for “Wnt oncoprotein” (see page 10164, left column). Note this teaching with the teachings of the instant specification at page 21-22: it is almost identical. Thus, teaching of Tanaka et al., suggest frizzled member proteins in tumor development and importance of extracellular domain of frizzled receptor for receptor-mediated signal for wnt-mediated oncogenic process. The disclosure of Tanaka et al., is similar in that the instant specification discloses frizzled 2 data (Fig. 5 and 6), while Tanaka et al., discloses frizzled 3 data. Both the instant application and Tanaka et al.,

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connects any Frizzled to Wnt signaling in terms of cancer development or cancer therapeutics.

As for applicant's argument that Hudziak patent is not about Frizzled 5 protein, Hudziak patent is cited to show that antibodies to a receptor has been used to inhibit the growth of tumor cells (column 5, lines 16 and 17) in the art and making and screening such antibodies are well within the knowledge of the ordinary skill in the art. Hudziak patent teaches that antibodies are selected using conventional in vitro assays for selecting antibodies which neutralize receptor function. This suggests that an antibody binding to extracellular domain, where the natural ligand binds to, would inhibit the function of the receptor. Hudziak patent also teaches assays to screen an antibody that inhibits growth of the malignant cell. Hudziak patent teaches a cytotoxic response and label at claims 1-39.

In addition, based on Noelle v. Lederman, 69 USPQZd 1508, 1514 (Fed. Cir. 2004), an antibody to known antigenic sequence is obvious, and one of skill would have been arrived at the claimed invention with a reasonable expectation of success, given the amino acid sequence has been known, the extracellular domain of a frizzled 5 is where the natural ligand binds to, had been well known in the art before the effective filing date of the instant application as taught by Tanaka et al., and also given that advantage of the antibody to extracellular domain and an assay to isolated an antibody inhibiting the growth of a malignant cell had been known in the art as taught by Hudziak patent well before the effective filing date of the instant application.

***The Following Are New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8, 16, 28 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Sen et al., #161 of IDS filed on 08/04/2003, Arthritis & Rheumatism vol. 44, pages 772-781.

Claims 1-8, 16, 28, and 29 are drawn to a purified antibody binds to an epitope at the N-terminal extracellular domain (SEQ ID NO: 68) or pharmaceutical comprising said antibody, wherein the antibody inhibits growth of a malignant cell expressing a frizzled 5 receptor.

Sen et al., teaches Fz5 signaling was blocked with an antibody to the extracellular domain of the receptor. Since the instant claim 5 says that the claimed invention is an antibody that interferes with the frizzled 5 receptor signaling pathway, the antibody disclosed in Sen et al., meets the limitation of the claimed invention.

The preamble recitation of pharmaceutical is merely suggestive of an intended use and for purposes of comparing the claims with the prior art, the claims read on the antibody *per se*.

As for the structural nature of the antigen, the instant SEQ ID NO: 68 appears to be same as what is known in the art as the extracellular domain of Fz5. In the absence

of evidence to the contrary, the burden is on the applicant to prove that the claimed SEQ ID NO: 68 is the extracellular domain of Fz5 taught by the prior art. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner  
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/MISOOK YU/  
Primary Examiner, Art Unit 1642